

Iris Diagnostics, A Division of IRIS International, Inc.

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MAR 23 2005

510(k) SUMMARY

510(k) Submission: K050235

iQ® 200 Urine Analyzer Body Fluids Module

General Information:

Date of Submission: January 31, 2005

Trade Name of Device: iQ® 200 Urine Analyzer Body Fluids Module

Common Name of Device: Instrument for performing RBC and nucleated cell counts in Cerebrospinal and Serous Body Fluids.

Classification Name: Automated cell counter,
21CFR 864.5200, Class II device

Submitter's Name: Harvey L. Kasdan, Ph.D.
Chief Scientist
Iris Diagnostics, A Division of
IRIS International, Inc.
9172 Eton Avenue, Chatsworth, CA 91311

Indications for Use (Brief): Cerebrospinal fluid analysis is ordered by physicians to diagnose meningitis, intracranial hemorrhage, leukemias, malignancies and central nervous system disorders. Serous fluid analysis is ordered by physicians to diagnose infections, hemorrhages, malignancies and other disorders. Cell count determination is a part of these analyses. The iQ® 200 Urine Analyzer Body Fluids Module is used by a competent human observer to examine and count red blood cells and nucleated cells in cerebrospinal fluid and serous fluids.

Intended Use: The iQ® 200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by a competent human observer to examine and count red blood cells and nucleated cells in cerebrospinal fluid and serous fluids. This module is a capability added to the iQ200 Urine Analyzer, a cleared urinalysis instrument (K022774).

**Substantial Equivalence
to Predicate Devices:**

The iQ®200 Urine Analyzer Body Fluids Module is substantially equivalent to Flow Microscopy of Pleural Fluid, Peritoneal Fluid and Peritoneal Dialysate in The Yellow IRIS Urinalysis Workstation (K914256), Flow Microscopy of Cerebrospinal Fluid and Seminal Fluid in The Yellow IRIS Urinalysis Workstation (K934539), Flow Microscopy of Synovial Fluid and Pericardial Fluid in The Yellow IRIS Urinalysis Workstation (K954006), and the Sysmex XE-2100 Series Hematology Analyzer Body Fluid Application (K040073), in its principles and technology, its automated functions and the participative involvement of a competent human observer, as well as to manual body fluid microscopic cell-count examination by a competent observer using a light microscope.

**Summary of
Technological
Characteristics:**

Two aliquots from each body fluid specimen sample are prepared. One aliquot is diluted in normal saline to provide a concentration in the linear range of the instrument. The second aliquot is treated with a lysing reagent to allow unambiguous identification of nucleated cells by eliminating RBC confusion. Particle images are captured and saved electronically as the sample flows past a microscope objective at a high speed, electronically concentrating particles. Particle images are then ordered by size into assigned categories on a video display. A competent human observer may change machine assignments, after which particle concentrations are recomputed and reported.

Performance Studies:

Microscopic cell counting performance of the iQ® 200 Analyzer Body Fluids Module was compared with manual chamber counting.

**Conclusions Drawn
From Clinical Tests:**

Clinical trial performance data demonstrated that the iQ® 200 Analyzer Body Fluids Module is substantially equivalent to the manual chamber counting method used for body fluid cell count determination. Regression analysis of all iQ®200 Analyzer Body Fluids Module CSF and Serous fluid sample cell counts on corresponding manual chamber counts yielded the following results with outliers removed:

Cell	Number of Samples	R ²	Slope	Slope 95% CI
RBC	304	0.992	0.906	0.896 – 0.915
Nucleated Cells (NC)	299	0.967	1.015	0.993 – 1.037

(RBC R² = 0.973 and NC R² = 0.940 with outliers.)

Non-zero intercepts were not statistically significant. Similar results were obtained for CSF and Serous Fluid alone. Paired t-tests showed that the mean difference between replicate cell counts was not statistically different from zero. NCCLS EP6-A protocol demonstrated linear response from 0 to 10,000 particles/microliter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Harvey L. Kasdan, Ph.D.
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of IRIS International, Inc.
9172 Eton Avenue
Chatsworth, California 91311

MAR 23 2005

Re: k050235
Trade/Device Name: iQ® 200 Urine Analyzer Body Fluids Module
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: II
Product Code: GKL
Dated: January 31, 2005
Received: February 1, 2005

Dear Dr. Kasdan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." with a stylized flourish at the end.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050235

Device Name: iQ® 200 Urine Analyzer Body Fluids Module

Indications for Use:

The iQ 200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by a competent human observer to examine and count red blood cells and nucleated cells in cerebrospinal fluid and serous fluids.

Cerebrospinal fluid analysis is ordered by physicians to diagnose meningitis, intracranial hemorrhage, leukemias, malignancies and central nervous system disorders. Serous fluid analysis is ordered by physicians to diagnose infections, hemorrhages, malignancies and other disorders. Cell count determination is a part of these analyses.

The information produced by the iQ 200 Urine Analyzer Body Fluids Module concerning the cell concentrations in CSF and serous body fluids is ordered at the discretion of the physician, and is part of a larger body of laboratory and other test results available to assist the physician in health assessments or differential diagnoses. Cell count findings are always subject to judgment and interpretation by physicians relative to the patient's overall clinical presentation and history.

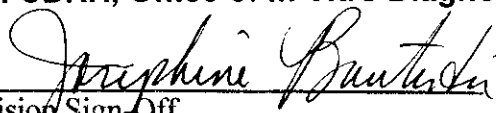
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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